(m) The term *all business trading names used by the establishment* means any name which is used on a cosmetic product label and owned by the cosmetic product manufacturer or packer, but is different from the principal name under which the cosmetic product manufacturer or packer is registered.

(n) The definitions and interpretations contained in sections 201, 601, and 602 of the act shall be applicable to such terms when used in the regulations in this subchapter.

(o) *System of commercial distribution* of a cosmetic product means any distribution outside the establishment manufacturing the product, whether for sale, to promote future sales (including free samples of the product), or to gage consumer acceptance through market testing, in excess of $1,000 in cost of goods.

(p) *Filed screening procedure* means a procedure that is:

(1) On file with the Food and Drug Administration and subject to public inspection;

(2) Designed to determine that there is a reasonable basis for concluding that an alleged injury did not occur in conjunction with the use of the cosmetic product; and

(3) Which is subject, upon request by the Food and Drug Administration, to an audit conducted by the Food and Drug Administration at reasonable times and, where an audit is conducted, such audit shows that the procedure is consistently being applied and that the procedure is not disregarding reportable information.

(q) *Reportable experience* means an experience involving any allergic reaction, or other bodily injury, alleged to be the result of the use of a cosmetic product under the conditions of use prescribed in the labeling of the product, under such conditions of use as are customary or reasonably foreseeable for the product or under conditions of misuse, that has been reported to the manufacturer, packer, or distributor of the product by the affected person or any other person having factual knowledge of the incident, other than an alleged experience which has been determined to be unfounded or spurious when evaluated by a filed screening procedure.

[39 FR 10054, Mar.15, 1974, as amended at 46 FR 38073, July 24, 1981]

Subpart B—Requirements for Specific Cosmetic Products

§ 700.10 Shampoo preparations containing eggs as one of the ingredients.

The present views of the Food and Drug Administration concerning the status of shampoo preparations containing egg as one of the ingredients are as follows:

(a) An article designated as ''egg shampoo'' should contain one egg (or the equivalent amount of dried whole egg) in that quantity of the article which would be used in one shampooing of the hair.

(b) An article that contains less than one egg per ''shampoo'' should not be referred to as an ''egg shampoo'' and the word ''egg'' should not be used as part of the name of the article. At the present time, the Food and Drug Administration is not raising objection to the marketing of an article containing less than one egg per ''shampoo,'' provided the word ''egg'' does not appear in the name of the article, the reference to the egg ingredient, such as ''plus egg,'' appears in a subordinate position on the label and is in type which is substantially reduced in size in comparison with the title of the article, and the reference to the presence of egg reveals the amount of the egg ingredient.

(c) In the case of an article containing less than 2 percent egg, the amount of egg is so small as to be insignificant, and it is therefore considered that it would be misleading for the labeling to make any mention of the presence of egg in such a product.

§ 700.11 Cosmetics containing bithionol.

(a) Bithionol has been used to some extent as an antibacterial agent in cosmetic preparations such as detergent bars, shampoos, creams, lotions, and bases used to hide blemishes. New evidence of clinical experience and photopatch tests indicate that bithionol is capable of causing